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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,016	03/12/2001	Evgenyi Y. Shalaev	PC10807ACJG	1570

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Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1653	4

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,016	SHALAEV ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7-13,15-18,20-22 and 24* is/are rejected.

7)☒ Claim(s) *2,4,6,14,19 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The disclosure is objected to because of the following informalities: At page 6, line 4, "comprise lyoprotectants" should be two words. Appropriate correction is required.

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use" is not a statutory class of invention.

3. Claims 1, 3, 5, 7, 8, 10-13, 15-18, 20-22, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the term "derivative" in claims 1, 3, 5, 7, 10-12, 15-17, and 20-22 is unclear because it not clear what degree of structural and/or functional similarity a compound must have with methoxysalicylaldehyde in order for the compound to be considered a "derivative" of methoxysalicylaldehyde and therefore embraced within the scope of Applicants' claims. For example, it is not clear if the methoxy, aldehyde, phenyl, and/or hydroxy groups must still be present in the derivatives. The term is not defined either in the specification or the art. Claim 24 is indefinite because it is not clear what constitutes a "Use", e.g., it is not clear if Applicants are claiming a product with an intended use limitation, or if Applicants are claiming a method of use. If the latter interpretation is intended, claim 24 is indefinite because it is directed to a method of use but does not recite any positive process steps.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 7-10 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Tyle et al (U.S. Patent No. 5,977,068). Tyle et al teach a combination of bovine growth hormone and 0.1 % w/v o-vanillin. See column 3, Table I.

6. Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al (U.S. Patent No. 5,198,422). Clark et al teach a combination of somatotropin and preferably from about 0.5% to about 5.0% by weight of an aromatic aldehyde which is preferably o-vanillin. See, e.g., column 2, lies 34-55.

7. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Carden (U.S. Patent No. 4,714,609). Carden teaches contacting skin, which comprises solid-state proteins including keratin and collagen, with a skin tanning composition comprising vanillin. See, e.g., the Abstract. Vanillin is a methoxysalicylaldehyde. The sun emits ionizing radiation. Because the same solid-state protein is being contacted with the same methoxysalicylaldehyde according to the same method steps, inherently the solid-state proteins in the skin of Carden will be protected from ionizing radiation to the same extent claimed by Applicants.

8. Claims 1, 7, 8, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson (U.S. Patent No. 5,730,933). Peterson teaches radiation sterilization of biologically active proteins or peptides by including an extraneous protein and a free radical scavenger. The free radical scavengers have a concentration of preferably about 0.1 to 5 weight percent. See, e.g., the Abstract; column 3, line 47 - column 4, line 1; column 4, lines 48-50; and column 6, lines 3-9. The free radical scavengers of Peterson are deemed to constitute methoxysalicylaldehyde derivatives because of their structural similarity (e.g., all are organic

compounds) and because of their functional similarity (e.g., they protect peptides and proteins during radiation sterilization).

9. Claims 1, 3, 7, 12, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated b Blank et al (U.S. Patent No. 5,789,396). Blank et al teach a composition comprising a combination of salicylic acid and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid and a pharmaceutically acceptable carrier. The composition is applied to skin, which comprises solid-state proteins including keratin and collagen, which is subject to exposure to ultraviolet radiation, i.e. ionizing radiation. See, e.g., column 1, lines 20-23; column 7, lines 5-11; and claims 1 and 2. Salicylic acid is a derivative of methoxysalicylaldehyde. With respect to instant claim 24, note that an intended use limitation does not impart patentability to a composition claim which is otherwise anticipated by the prior art.

10. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over Blank et al (U.S. Patent No. 5,789,396). Application of Blank et al is the same as in the above rejection of claims 1, 3, 7, 12, 22, and 24. Blank et al teach compositions comprising salicylic acid and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and teach that the pharmaceutically acceptable carriers can include isopropanol (see, e.g., column 9, line 56), but does not teach the particular combination of salicylic acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, and isopropanol. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use isopropanol as the pharmaceutically acceptable carrier for the combination of salicylic acid and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid taught by Blank et al because Blank et al disclose isopropanol to be a useful pharmaceutically

acceptable carrier and because the choice of the carrier would not have been expected to affect significantly the actions of the active ingredients of Blank et al.

11. Claims 2, 4, 6, 14, 19, and 23 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 13, 15, 16, 18, 20, and 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. With respect to instant claims 2, 4, and 6, the prior art of record does not teach or suggest combining a protein with 3-methoxysalicylaldehyde and then exposing the combination to ionizing radiation. The vanillin of Carden, the free radical scavengers of Peterson, and the salicylic acid of Blank et al do not suggest 3-methoxysalicylaldehyde, nor does the prior art of record teach or suggest vanillin, free radical scavengers, and/or salicylic acid to be functional equivalents of 3-methoxysalicylaldehyde. With respect to instant claims 13 and 18, the proteins present as part of the skin treated by Blank et al are not drugs. With respect to instant claims 15, 16, 20, and 21, when the weight of the proteins in the skin is taken into account, Blank et al do not teach or suggest the salicylic acid concentrations which would be required by these claims. With respect to claim 23, the prior art of record does not teach or provide any motivation to combine 3-methoxysalicylaldehyde with 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

September 17, 2002